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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,585	07/25/2005	John W. Morris	285-323 PCT US	2545
25763 7590 03/03/2010 DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498				
EXAMINER SINGH, ANOOP KUMAR				
ART UNIT 1632		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,585

Applicant(s)

MORRIS ET AL.

Examiner

ANOOP SINGH

Art Unit

1632

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 4-25 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9 and 11-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 2, 4- 7, 10, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Examiner prosecuting this application has been changed. Any inquiries relating to the examination of the application should be directed to Examiner Singh. The telephone number is provided at the end of this office action.

Applicants' arguments filed October 30, 2009 have been received and entered. Claims 1, 2, 4-25 are pending in the application.

This action is Non-Final.

Election/Restrictions

Applicant's election of Group I in the reply filed on 10/12/07 was acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election was treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 8, 9, 11-23 remain withdrawn from consideration for being directed to non-elected subject matter. Claims 1- 2, 4- 7, 10, 24 and 25 are currently under examination.

Withdrawn-Claim Rejections - 35 USC § 102

Claims 1, 2, 4, 5, 7, 10, 24 and 25 were rejected under 35 U.S.C. 102(b) as being anticipated by Dowd et al (US 5507813). Applicants' argument that Dowd et al fails to teach solidifying the immobilization medium to provide solidified mass of bone and medium is persuasive; therefore, the previous rejections of claims 1, 2, 4, 5, 7, 10, 24 and 25 are hereby withdrawn. Applicants' arguments with respect to the withdrawn rejections are thereby rendered moot. The claims are however subject to new rejections over the prior art of record, as set forth below.

Claims 1, 2, 4, 5, 10, 25 were rejected under 35 U.S.C. 102(e) as being anticipated by Sherwood et al (US 6454811B1). Applicants' argument that Sherwood et

al fails to teach solidifying the immobilization medium to provide solidified mass of bone and medium and separating bone particle from the immobilization medium is persuasive; therefore, the previous rejections of claims 1, 2, 4, 5, 10, 25 are hereby withdrawn. Applicants' arguments with respect to the withdrawn rejections are thereby rendered moot. The claims are however subject to new rejections over the prior art of record, as set forth below.

Maintained- Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-7, 24 remain rejected under 35 U.S.C. 102(e) and claim 10 is also rejected as being anticipated by Boyce et al. (US 6863694, dated 3/8/2005, filed 7/3/2000)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. It should be noted that bone particle is interpreted as fragment of a bone.

Boyce et al. disclose a method of making osteogenic osteoimplant by using bone derived elements. Boyce et al. disclose that the bone derived elements may be at least partially demineralized or fully demineralized or any combination of the foregoing (see for example, col.7, 3rd paragraph, line 1-3). Boyce et al. also disclose that the bone derived elements is mixed with a fluid carrier, such as water or glycerol, and additional

optional ingredients (see col. 12, last paragraph, and col. 13, 1st and 2nd paragraph) to form a dough-like composition. Boyce et al. further disclose that this composition may subject to mechanical shaping, and then subdivided into sections suitable for implant (see col. 14, lines 23-26, lines 53-57, and col. 16, lines 63-65). Boyce et al. also disclose that this composition is preferably dehydrated, e.g. lyophilized, and/or frozen prior to packaging for use (see col. 14, lines 62-67). The disclosure of Boyce et al. anticipates the claimed method because it discloses every step of the method.

Response to arguments

Applicants disagree with the rejection and argue that Boyce does not teach "solidifying the immobilization medium to provide a solidified mass of bone and immobilization medium" as presently claimed. Applicants assert that Boyce teaches "bone derived elements..., mixed with a fluid carrier..., to form a dough-like composition." This is not "solidification of an immobilization medium." Nor is Boyce's "dough-like composition" "a solidified mass of bone and immobilization medium. Applicants' arguments have been fully considered, but are not found persuasive.

As an initial matter, it should be noted that the term solidifying the immobilization medium is interpreted as a process of changing liquid to solid phase. Therefore, any stage in between the liquid and solid process is interpreted as a process of solidifying the medium. Likewise, "to provide solidified mass" is interpreted as a process to become solid. Applicants should note that solidifying the medium to provide solidified mass read on a process that changes liquid to putty, dough or even paste that is a process of solidifying in order to make a solidified mass. Contrary to applicants' assertions mixing bone particles with a fluid carrier to form a dough-like composition is a process of solidifying the immobilization medium. It should be noted that upon mixing bone particle with the immobilization medium, the liquid phase is changed to a phase that is towards solidifying the medium to provide a solidified mass relative to original liquid phase. In the instant case, dough is considered solidified mass relative to the original liquid phase. It should be noted that claim does not require any specific method of solidifying (for instance, freezing) the immobilization medium nor does it requires to

provide a solid mass of immobilization medium. Therefore, disclosure of Boyce et al. anticipates the claimed method because it discloses every step of the method.

New-Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 2, 4-7, 10, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce et al (US Patent no 5,899,939, dated 5/4/1999), Dowd et al (US 5507813, dated 4/16/1996, art of record) and Aaron et al (J Histochem Cytochem. 1987 Mar;35(3):361-9).

With respect to claims 1, 2, 4-5, 7, 10, Boyce et al teach subdividing a cortical section of bone from the diaphyseal region and then immersed in immobilization medium water that is then solidified by freezing at -70°C and then freeze-dried for 2 days to separate the bone particle from water. It is further disclosed that that multilayered unitary structure is then cut to provide the shape of bone implant (example 1). While Boyce et al teach immersing a bone in water, solidifying the water and bone by freezing and then subsequently freeze drying to separate the bone particle from the water, but differ from claimed method by not explicitly teaching subdividing the solidified mass to provide subdivided bone particle prior to freeze drying.

Dowd et al. disclose a method for preparing the shaped osteogenic materials by using a quantity of bone particles that has been demineralized, slurried in a suitable liquid, e.g., water, organic protic solvent, aqueous solution such as physiological saline, etc., and optionally containing one or more biocompatible ingredients such as adhesives, fillers, plasticizers (eg. Glycerol), flexibilizing agents, that is applied to a form such as a flat sheet, mesh screen or three-dimensional mold and excess liquid is

removed, e.g., by being drained away (see col. 3, lines 25-30, col. 4, line 9). The wet demineralized bone particles are then subject to lyophilization in accordance with procedures and conditions that are well known in the art, e.g., a shelf temperature of from about -20.degree to about -35.degree. C., a vacuum of from about 150 to about 100 mTorr for a time of from about 4 to about 48 hours depending on the mass. Dowd et al. further disclose that at the site of implantation, the shaped article can be employed in the dry state or, where site conformation is desired, in the hydrated state. It is noted that Dowd et al disclose that dry or hydrated article can be cut or sized if need be to conform to a site being repaired (see col. 4, line 48 to col. 5, lines 1-27), therefore the teaching of Dowd embrace subdividing the dry mass of bone and solidified medium using routine methods known in prior art and evidenced by Aaron et al who reported freezing bone and immersion medium that is subsequently subdivided using microtome (see figure , page 362, col. 2, para. 1-3).

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Boyce et al, Dowd and Aaron to modify the method of Boyce by subdividing the frozen immobilization medium and bone prior to freeze drying using the method known in art (see Dowd and Aaron), as a matter of design choice, in the method of making bone particles, as instantly claimed, with a reasonable expectation of success, at the time of the instant invention. Said design choice amounting to combining prior art elements according to known methods to yield predictable results. One of ordinary skill in the art would be motivated to do so as Aaron teaches that freezing immobilization medium act as an embedding medium resulting in more efficient cutting of bone specimen (see page 362, col. 2, para. 1). Other limitation of using demineralized whole bone or section would be obvious modification of the method of Boyce in view of method for preparing the demineralized bone disclosed by Dowd. One of skill in the art would have been expected to have a reasonable expectation of success in subdividing the solidified mass of bone and medium because the freezing immobilization medium would support and act as an embedding medium for efficient cutting of the bone particles and because the art teaches successfully subdividing frozen immersion medium and bone. It should be noted that the *KSR* case

forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness See the recent Board decision *Ex parte Smith*, -- USPQ2d--, slip op. at 20, (Bd. Pat. App & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396, www.uspto.gov/web/offices/dcom/bpail/prec/fd071925.pdf).

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anoop Singh/
Examiner, Art Unit 1632